

JUL 31 2002 09:43 FR 4TH FLOOR SVC CENTER

TO 14060#3194900002 P.03/23

PATENTS
DOCKET NO. 31949/2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Joseph A. Leveque
Serial No.: 09/754,743
Filed: 01/04/2001
Title: Collecting And Managing Clinical Information
Art Unit: 2163
Examiner:

Box 1'GPUB Drawings
Commissioner For Patents
Washington, D.C. 20231

PETITION UNDER 37 C.F.R. § 1.182

Applicant hereby petitions under 37 C.F.R. § 1.182 for entry of the attached replacement drawings so that publication of this application will include the attached drawings instead of the informal drawings previously filed in this case.


This paper is being filed within the later of one month from the filing of this application or fourteen months from the earliest filing date for which benefit is sought in this application.

The Director is hereby authorized to charge \$130, the fee that is due in this case under 37 C.F.R. § 1.17(h), and to charge any other fees that may be due in connection with this paper, or credit any overpayment of the same, to Deposit Account No. 50-0324. A duplicate copy of this paper is enclosed.

Respectfully submitted,



Matthew T. Byrne
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<p>Certificate of Mailing I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:</p> <p>Commissioner for Patents Washington, D.C. 20231</p> <p>(Date) <u>3/1/02</u></p> <p>Typed or printed name of person signing this certificate <u>Matthew T. Byrne</u></p> <p>Signature: </p>

NYDOCS04/338388.1

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Commissioner for Patents
Washington, DC 20231
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6/24/02

Shearman and Sterling
Intellectual Property Docketing
599 Lexington Avenue
New York NY 10022

Dear Applicant:

The Box PGPub replacement drawings for application number 09/754,743 received on 3/11/02 by the U. S. Patent and Trademark Office will be included in the application file but **will not** be included for patent publication due to the following reason(s):

- 1) ☐ Non compliance:
 - ☐ Drawing(s) and/or Figure(s) Missing
 - ☐ Deficiencies in Drawings:
 - ☐ Improper paper size - must be either A4 (21cm x 29.7cm) or 8-1/2" x 11"
 - ☐ Improper margins (each drawing sheet must include a top margin of at least 1 inch, a left side margin of at least 1 inch, a right side margin of at least 5/8 inch, and a bottom margin of at least 3/8 inch)
 - ☐ Not reproducible:
 - ☐ Paper too thin
 - ☐ Glossy pages
 - ☐ Non-white background
 - ☐ Drawing Objection(s)
 - ☐ Missing lead lines, drawing(s) _____
 - ☐ Line quality is too light, drawings(s) _____
 - ☐ More than 1 drawing and not numbered correctly
 - ☐ Non-English text, drawing(s) _____



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- ☐ Excessive text, drawing(s) _____
- ☐ Photographs capable of illustration, drawing(s) _____
- ☐ Photographs may not be mounted (must be developed on a sheet of paper meeting the paper size requirement). 37 CFR 1.85(e)

2) ☐ Submission Did Not Meet Fee Requirements

- ☐ No Fee
- ☐ Insufficient fee by check
- ☐ Insufficient funds in deposit account
- ☐ Declined credit card
- ☐ Non authorization for charge to deposit account

3) ☒ Untimely Submission

If you desire to have replacement drawings included for patent publication, you must submit new drawings, a petition, the petition fee of \$130 and a transmittal letter. The new submission must be submitted to the U. S. Patent and Trademark Office within the later of one month from the filing date of the application, or fourteen months from the earliest filing date for which a benefit is sought under title 35, United States Code.

Telephone inquiries should be directed to Customer Service, Office of Initial Patent Examination, at 703-308-1202.



Signature of Reviewer, Office of Initial Patent Examination

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TO 14060#3194900002 P.01/23

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Communications Dept. Telephone: (212) 848 8434

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51949,00002

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Comments:

2 Copies of Box PGRob Petition and
Notice from PTO in response thereto attached.
Thanks for looking into this. Best regards,
Matt Byrne

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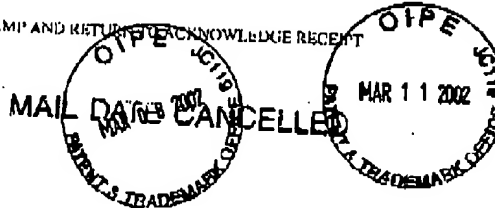
Date: March 1, 2002 Atty. Docket No. 31949/2
In re Application of Joseph A. Leveque et al.
Application No.: 09/754,743
Filed: January 4, 2001

Date: March 1, 2002 Atty. Docket No. 31949/2
In re Application of Joseph A. Leveque et al.
Application No.: 09/754,743
Filed: January 4, 2001
FOR: Collecting and Managing Clinical Information

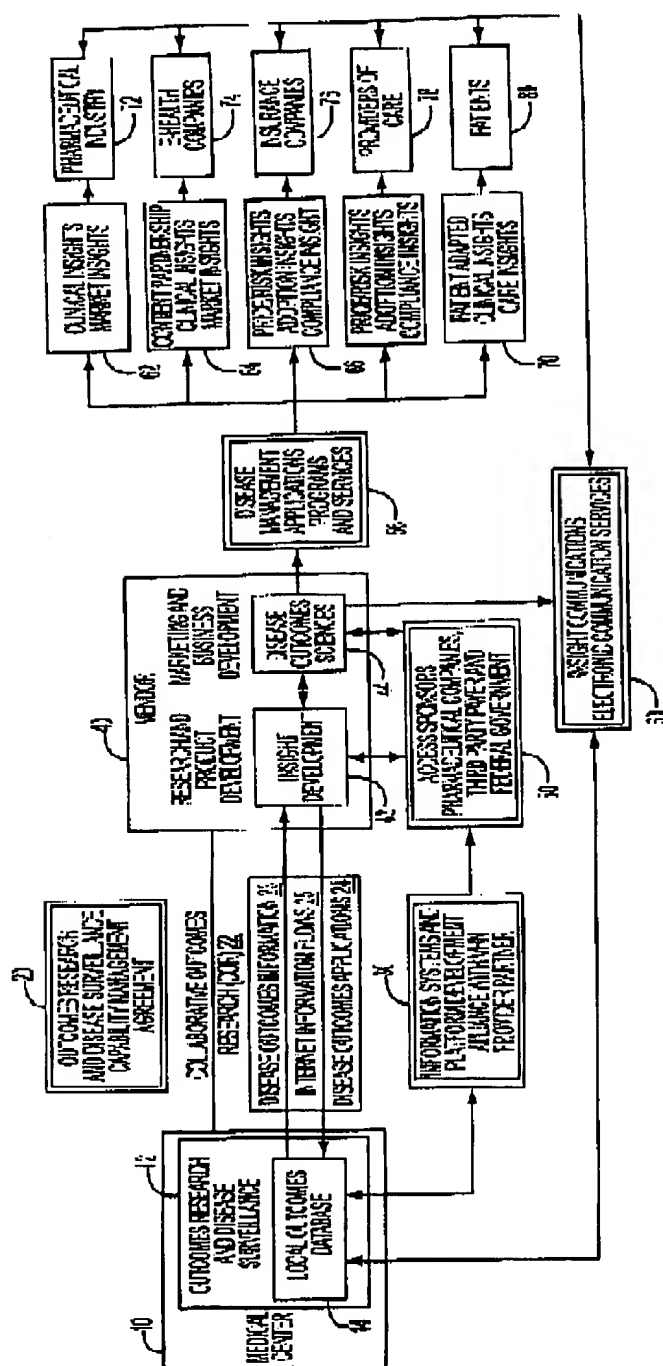
Envelopes

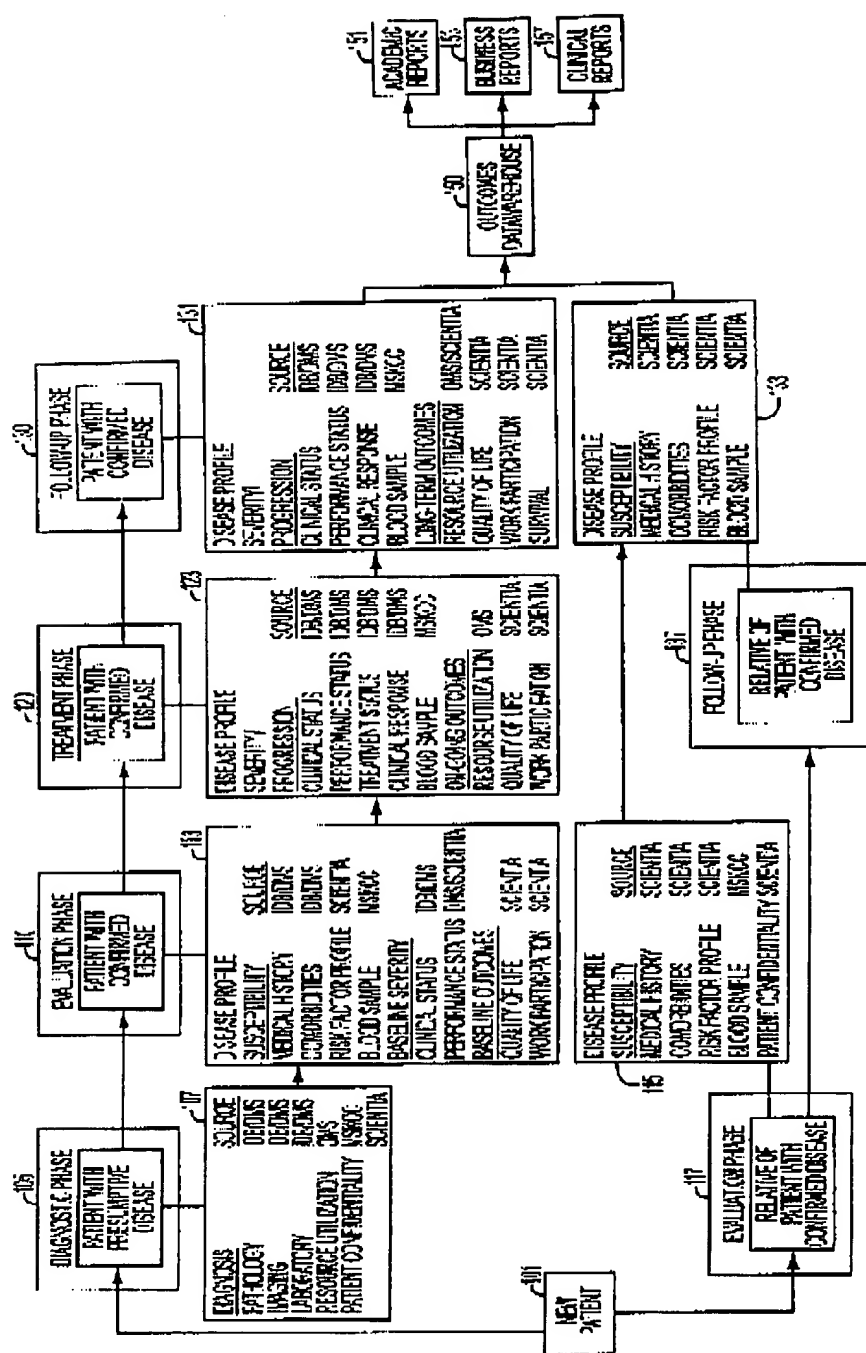
1. Petition Under 37 C.F.R. § 1.182 for entry of replacement drawings (1 page)(in duplicate); and
2. Replacement Drawings (18 Sheets).

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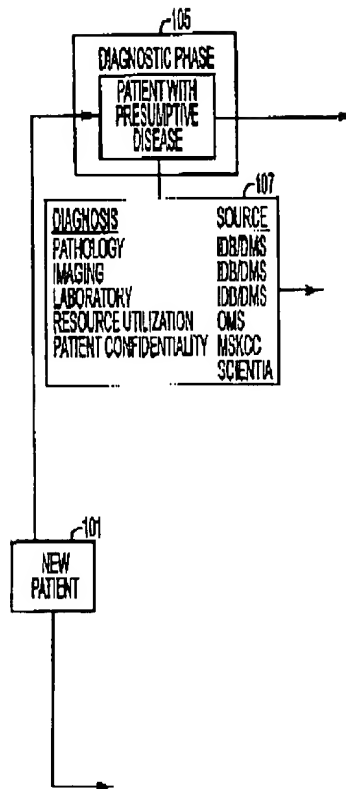


FIG. 3a

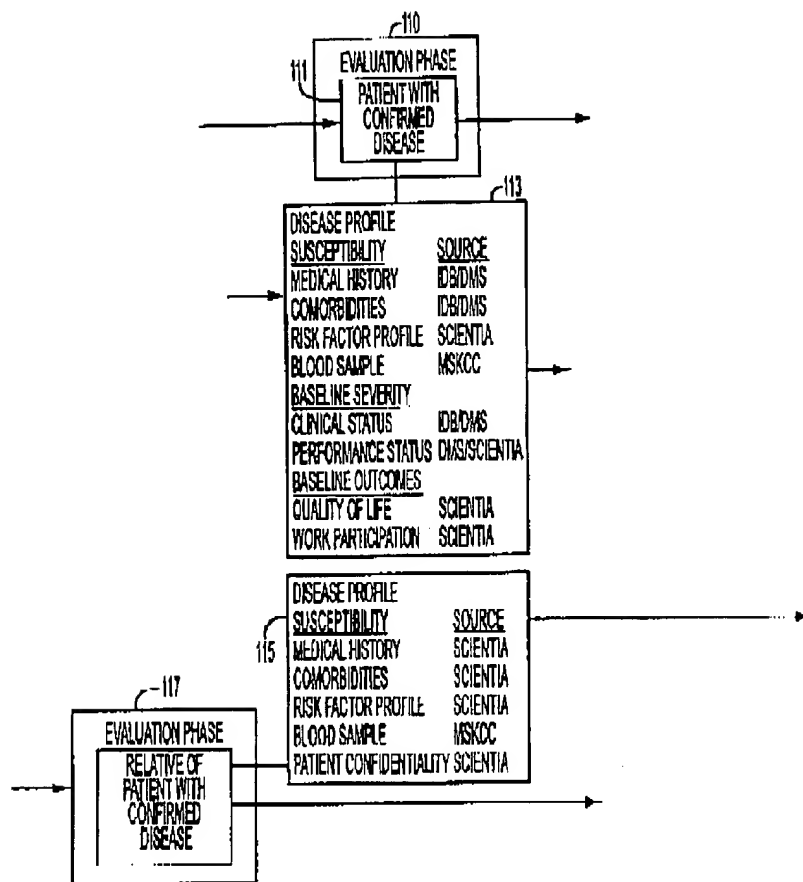


FIG. 3b

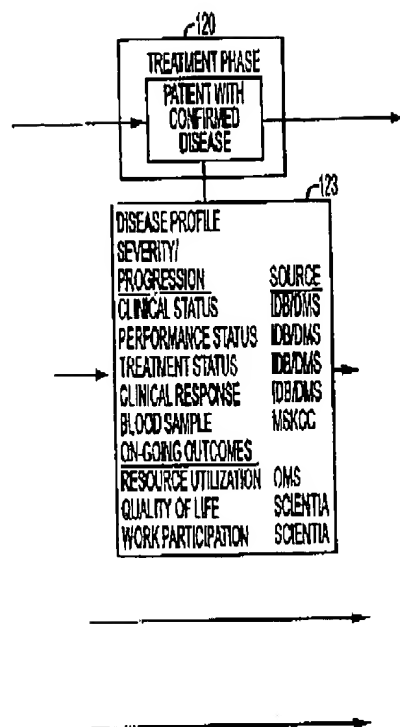


FIG. 3c

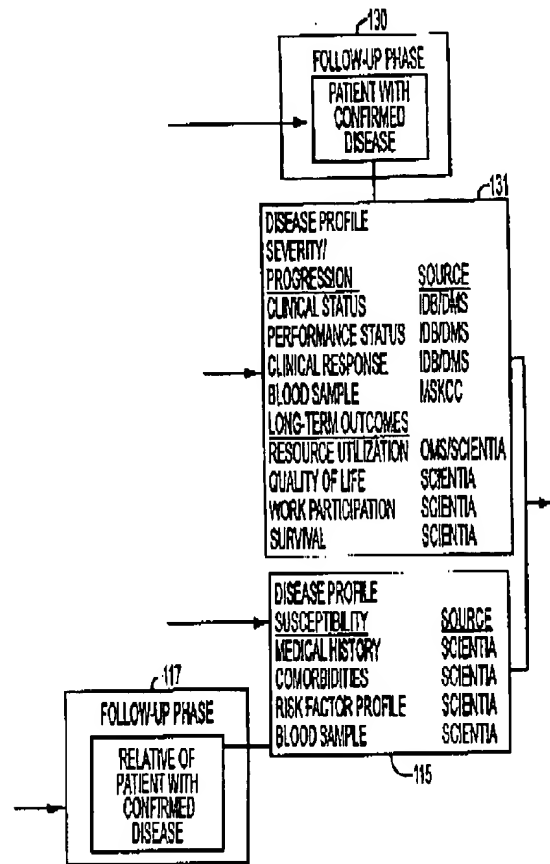


FIG. 3d

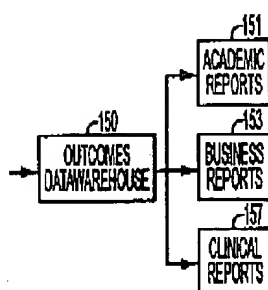


FIG. 3e

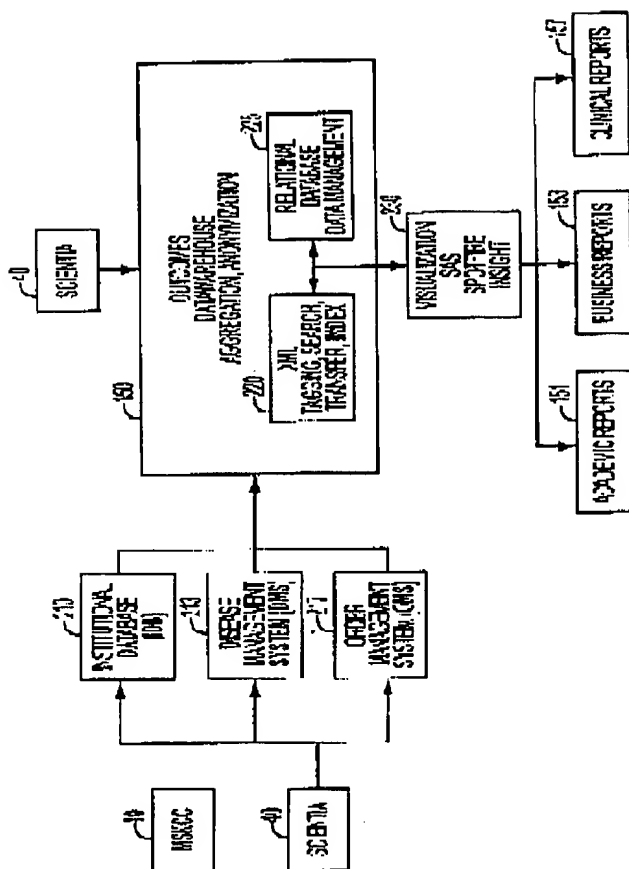


FIG. 4

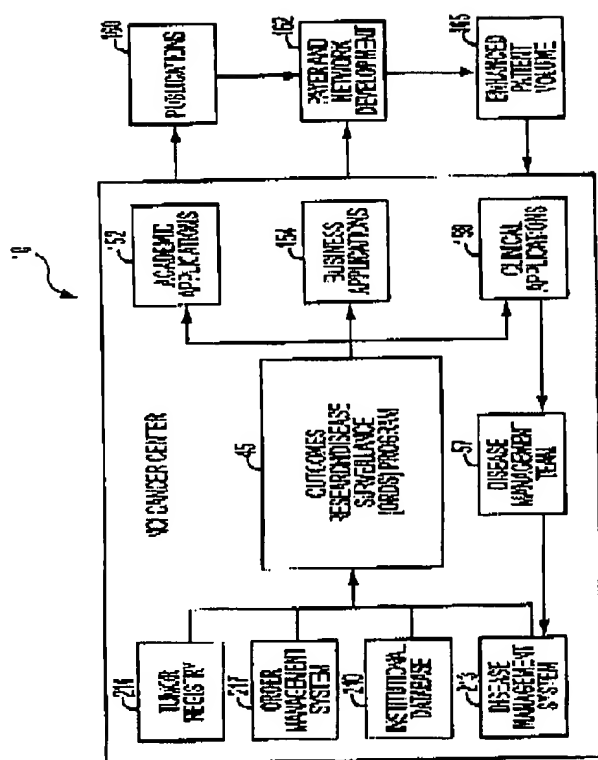


FIG. 5a

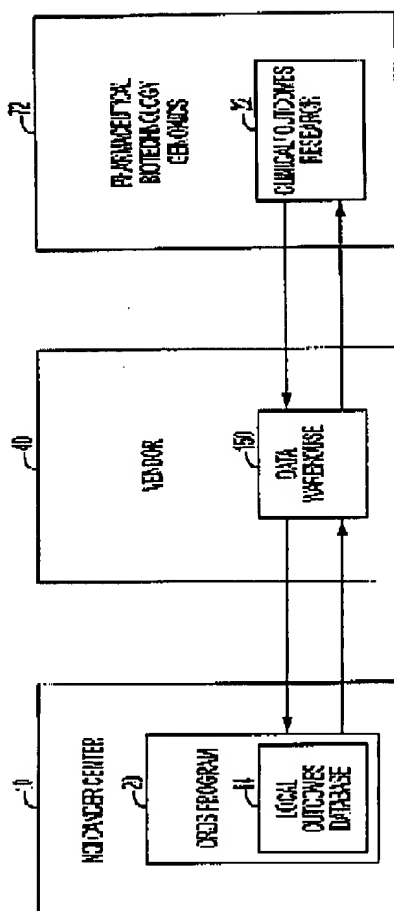


FIG. 5b

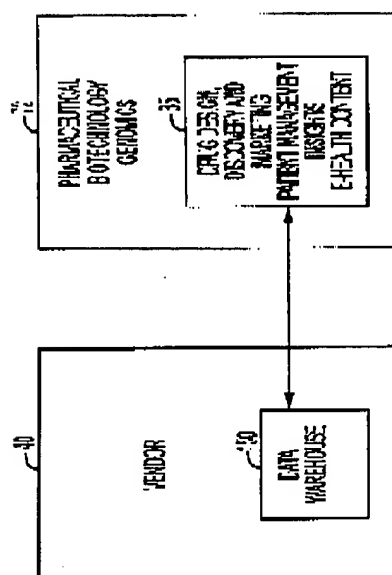


FIG. 5C

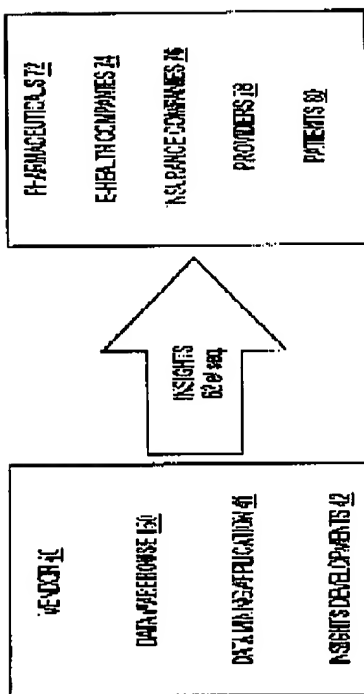


FIG. 5d

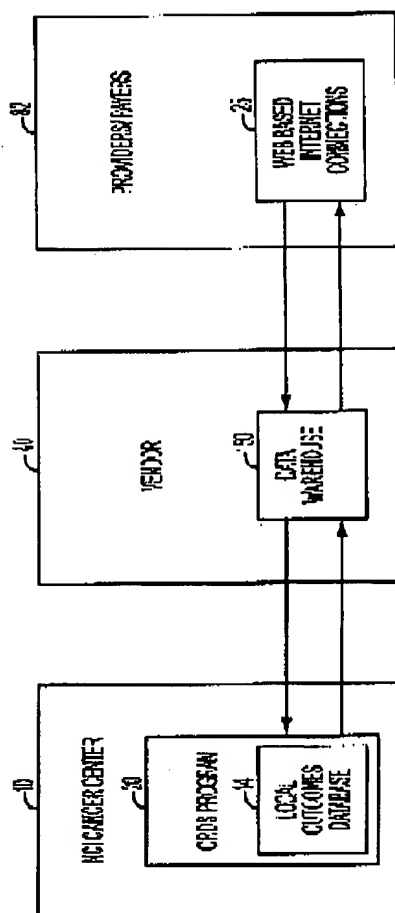


FIG. 5e

PATIENT CHARACTERISTICS	CLINICAL RESPONSE		
	COMPLETE RESPONSE	PARTIAL RESPONSE	OVERALL RESPONSE
DEMOGRAPHICS			
AGE			
PATHOLOGY			
TUMOR SIZE			
HISTOLOGY (1)			
ESTROGEN RECEPTOR STATUS (2)			
SITE OF METASTASIS			
CLINICAL STATUS			
DISEASE STAGE (3)			
MENOPAUSAL STATUS (4)			
PRIOR TREATMENT STATUS			
SURGICAL (5)			
CHEMOTHERAPY (6)			
RADIOTHERAPY			
TREATMENT STATUS			
COMPLICATIONS/TOXICITY (7)			
PERFORMANCE STATUS (8)			
TIME TO PROGRESSION/TREATMENT FAILURE			
(1) INfiltrating Ductal, Lobular (Small-Cell), Medullary, Tubular, Squamous Cell, Adenocarcinoma, Angiosarcoma (2) POSITIVE OR NEGATIVE ESTROGEN RECEPTOR (3) TNM STAGING CRITERIA (4) PRE- OR POSTMENOPAUSAL (5) RADICAL MASTECTOMY, MODIFIED RADICAL MASTECTOMY, LIMITED EXCISION (LUMPECTOMY) (6) CMF (CYCLOPHOSPHAMIDE, METHOTREXATE, 5-FLUOROURACIL), CA (CYCLOPHOSPHAMIDE AND DOXORUBICIN), TAMOXIFEN (7) NCI COMMON TOXICITY SCALE-HEMATOPOIETIC (LEUKOPENIA, NEUTROPENIA, ANEMIA, THROMBOCYTOPENIA), INFECTIOUS (FEVER, LOCALIZED INFECTION, SEPSIS), NEUROLOGICAL, ENDOCRINE (HYPER- OR HYPOGLYCEMIA), CARDIAC (CHF), CONSTITUTIONAL (NAUSEA, VOMITING, MALNUTRITION, STOMATITIS, LETHARGY, MALAISE) (8) KARNOFSKY			

FIG. 6a

PATIENT CHARACTERISTICS	RESPONSE				
	COMPLETE		PARTIAL	OVERALL	
	CLINICAL	RESOURCE USE	QOL	QALYs	WORK PARTICIPATION
DEMOGRAPHICS					
AGE					
PATHOLOGY					
TUMOR SIZE					
HISTOLOGY (1)					
ESTROGEN RECEPTOR STATUS (2)					
SITE OF METASTASIS					
RISK/PROGNOSTIC FACTORS					
FAMILY					
GENETIC SUSCEPTIBILITY					
APC					
AR					
AT					
BCL1					
BCL2					
BRCA1					
BRCA2					
CTSD					
EGF					
EGFR					
HRAS					
IGF1R					
LMYC					
NM23					
PS3					
SRC					
PRIOR HISTORY					
IN SITU					
INVASIVE					
ATYPICAL HYPERPLASIA					
ENDOGENOUS ENDOCRINE FACTORS					
AGE AT MENARCHE					
AGE AT MENOPAUSE					
AGE AT FIRST PREGNANCY					
EXOGENOUS ENDOCRINE FACTORS					
HORMONE REPLACEMENT THERAPY					
ORAL CONTRACEPTIVES					
ENVIRONMENTAL FACTORS					

FIG. 6b-1

CLINICAL STATUS
 DISEASE STAGE (3)
 MENOPAUSAL STATUS (4)
 PRIOR TREATMENT STATUS
 SURGICAL (5)
 CHEMOTHERAPY (6)
 RADIOTHERAPY
 TREATMENT STATUS
 COMPLICATIONS/TOXICITY (7)
 PERFORMANCE STATUS (8)
 TIME TO PROGRESSION/TREATMENT FAILURE
 SURVIVAL

(1) INfiltrating Ductal, Lobular (Small Cell), Medullary, Tubular, Squamous Cell, Adenocarcinoma, Angiosarcoma
 (2) POSITIVE OR NEGATIVE ESTROGEN RECEPTOR
 (3) TNM STAGING CRITERIA
 (4) PRE- OR POSTMENOPAUSAL
 (5) RADICAL MASTECTOMY, MODIFIED RADICAL MASTECTOMY, LIMITED EXCISION (LUMPECTOMY)
 (6) CMF (CYCLOPHOSPHAMIDE, METHOTREXATE, 5-FLUOROURACIL), CA (CYCLOPHOSPHAMIDE AND DOXORUBICIN), TAMOXIFEN
 (7) NCI COMMON TOXICITY SCALE-HEMATOPOIETIC (LEUKOPENIA, NEUTROPENIA, ANEMIA, THROMBOCYTOPENIA), INFECTIOUS
 (FEVER, LOCALIZED INFECTION, SEPSIS), NEUROLOGICAL, ENDOCRINE (HYPER- OR HYPOGLYCEMIA), CARDIAC (CHF), CONSTITUTIONAL
 (NAUSEA, VOMITING, MALNUTRITION, STOMATITIS, LETHARGY, MALAISE)
 (8) KARNOFSKY

FIG. 6b-2

PATIENT CHARACTERISTICS	RESPONSE				
	COMPLETE		PARTIAL	OVERALL	
	CLINICAL	RESOURCE USE	QOL	QALYS	WORK PARTICIPATION
DEMOGRAPHICS					
AGE					
PATHOLOGY					
TUMOR SIZE					
HISTOLOGY					
INFILTRATING DUCTAL					
LOBULAR					
MEDULLARY					
TUBULAR					
SQUAMOUS CELL					
ADENOCARCINOMA					
ANGIOSARCOMA					
OTHER					
ESTROGEN RECEPTOR STATUS					
POSITIVE					
NEGATIVE					
SITE OF METASTASIS					
NODES					
LUNG					
BONE					
BRAIN					
LIVER					
SKIN/SOFT TISSUE					
ADRENAL					
OTHER					
CLINICAL STATUS					
DISEASE STAGE					
STAGE 0					
STAGE I					
STAGE IIA					
STAGE IIB					
STAGE IIIA					
STAGE IIIB					
STAGE IV					
MENOPAUSAL STATUS					
PREMENOPAUSE					
POSTMENOPAUSE					

FIG. 6c-1

PRIOR TREATMENT STATUS
SURGICAL
RADICAL MASTECTOMY
MODIFIED RADICAL MASTECTOMY
LIMITED EXCISION
OTHER
CHEMOTHERAPY
CMF
CA
TAMOXIFEN
OTHER
RADIOTHERAPY
TREATMENT STATUS
COMPLICATIONS/TOXICITY
HEMATOPOETIC
INFECTIOUS
NEUROLOGICAL
ENDOCRINE
CARDIAC
CONSTITUTIONAL
PERFORMANCE STATUS
TIME TO PROGRESSION/TREATMENT FAILURE
SURVIVAL

FIG. 6c-2